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OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.) Klein et al.; "Improving Clinical Trials" American Society of Clinical Psychopharmacology /E.S./ Recommendations, Arch Gen Psychiatry/Vol. 59, March 2002, pp. 272-278. Doody et al.; "Open-Label, Multicenter, Phase 3 Extension Study of the Safety and Efficacy of Donepezil in Patients With Alzheimer Disease", Arch Neurol/Vol. 58, March 2001, pp. 427-433. /E.S./ Grandi; "The Sequential Parallel Comparison Model: A Revolution in the Design of Clinical Trials", Affective Disorders Program, Department of Psychology, University of Bologna, Bologna, Italy, Psychotherapy and Psychosomatics 2003; 72:113-114. /E.S./ Laughren; "The scientific and ethical basis for placebo-controlled trials in depression and schizophrenia: an FDA perspective", Eur Psychiatry 2001; 16: 418-23. /E.S./ Holbrook et al.; "Innovation and placebos in research: a new design of clinical trial", The Lancet, Vol. /E.S./ 362, December 20/27, 2003, pp. 2036-2037. Koch et al.; "A Two-Period Crossover Design For The Comparison Of Two Active Treatments And Placebo", Statistics In Medicine, Vol. 8, 487-504 (1989). /E.S./ Noseworthy et al.; "The impact of blinding on the results of a randomized, placebo-controlled multiple sclerosis clinical trial" American Academy of Neurology, 1994; 44;16-18. /E.S./ Streiner; "Placebo-controlled trials: when are they needed?" Schizophrenia Research 35 (1999), 201-210. /E.S./ Talbot; "The Placebo Prescription", New York Times Magazine, January 9, 2000, 10 pages. /E.S./ Hrobjartsson et al.; "Is the placebo powerless? Update of a systematic review with 52 new randomized trials comparing placebo with no treatment", Journal of Internal Medicine 2004; 256:91-100. /E.S./ Hart; "The mysterious placebo effect", Modern Drug Discovery, July/August 1999, 2 (4) 30-40, 7 pages. /E.S./ Faraone et al.; "The Drug-Placebo Response Curve: A New Method for Assessing Drug Effects in Clinical Trials", Journal of Clinical Psychopharmacology: December 2000 – Volume 20 – Issue 6 – pp. 673-679. /E.S./ Nordenberg; "The Healing Power of Placebos", The Body, FDA Consumer, January/February 2000, 6 /E.S./ pages. Zelen; "A New Design For Randomized Clinical Trials", The New England Journal of Medicine, Vol. 300, No. 22, May 31, 1979, pp. 1242-1245. E.S./ Hrobjartsson et al; "Is the Placebo Powerless? An Analysis of Clinical Trials Comparing Placebo with No Treatment", The New England Journal of Medicine, Vol. 344, No. 21, May 24, 2001, pp. 1594-1603 /E.S./ Ellenberg; "Randomization Designs In Comparative Clinical Trials", The New England Journal of Medicine, Vol. 310, No. 21, May 24, 1984, 1404-1408. /E.S./ Beller et al.; "Randomisation in clinical trials", MJA, Vol. 177, November 18, 2002, 565-567. E.S./ Altman et al.; "Statistics notes How to randomize", BMJ, Volume 319, September 11, 1999, 703-704. /E.S./ Examiner /Eliza Squires/ Date Considered: 10/07/2009 *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.

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